Exhibit #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K081757

1. **Submitter's Identification:**

AUG 15 2008

Verista Imaging, Inc.
22111 230th Avenue
Centerville, Iowa 52544

Telephone: (641) 856-5779

Contact: Mr. Kevin Wiskus

Date Summary Prepared: June 6, 2008

2. **Name of the Device:** Verista Imaging ISOCAM II Gamma Camera

3. **Common or Usual Name:** Scintillation (Gamma Camera)

4. **Predicate Device Information:**

K940487, ISOCAM II (Dual Head Gamma Camera), Independent Scintillation Imaging Systems, Inc.
K964834, ISOCAM II (Dual Head Gamma Camera), Park Medical Systems, Inc., Lachine, Quebec, Canada
K970128, ISOCAM I (Single Head Gamma Camera)/ISOCAM II (Dual Head Gamma Camera), Park Medical Systems, Inc., Lachine, Quebec, Canada

5. **Device Description:**

The modified Verista Imaging ISOCAM II Gamma Camera and the predicate devices are intended to image the distribution of radionuclides in the body by means of photon radiation detector(s).

The ISOCAM II Gamma Camera is a medical imaging device used in nuclear medicine. It produces gamma ray distribution emitting radionuclides. It consists of one or more detectors mounted on a gantry that is connected to an acquisition system for operating the camera and storing the images. The base unit is a nuclear imaging device which utilizes gamma ray scintillation technologies. The modification to the device is limited to an upgrade to the mechanical operation of the device. The modifications improve patient safety through changes to the arm drive mechanical components and the addition of a weighted counter balance system.

The base unit is a nuclear imaging device which utilizes gamma ray scintillation technologies. The modification to the device is limited to an upgrade to the mechanical operation of the device. The modifications improve patient safety through changes to the arm drive mechanical components and the addition of a weighted counter balance system.

6. Intended Use:

Verista Imaging ISOCAM II Gamma Camera is intended to image the distribution of radionuclides in the body by means of photon radiation detector(s).

7. Comparison to Predicate Devices:

The base device pf the modified Verista Imaging ISOCAM II Gamma Camera has the same technological characteristics as the predicate gamma cameras. The software contained in the subject device has not been modified as a result of the modifications made to the device and remains identical to the software contained in the predicate device(s). The modifications made to the subject device do not raise any new issues of safety or effectiveness.

8. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Verista Imaging, Inc. has conducted testing to verify and validate the changes made to the previously cleared Park Medical Systems ISOCAM Gamma Camera.

9. Discussion of Clinical Tests Performed: Not Applicable

10. Conclusions:

Verista Imaging's ISOCAM II Gamma Camera that is the subject of this submission is a modification to the previously marketed Park Medical System's ISOCAM Gamma Cameras, to re-design an arm drive mechanism. The modified subject device has the

same intended use and indications for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device(s). Thus, the modified subject device is substantially equivalent to the predicate device(s).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Verista Imaging, Inc
% Ms. Susan D. Goldstein-Falk
Official Correspondent
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
GREAT NECK NY 11021

Re: K081757
Trade/Device Name: Verista Imaging ISOCAM II Gamma Camera
Regulation Number: 21 CFR 892.1100
Regulation Name: Scintillation (gamma) camera
Regulatory Class: II
Product Code: IYX
Dated: July 31, 2008
Received: August 1, 2008

Dear Ms. Glodstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Exhibit D

Indications for Use

510(k) Number (if known): K081757

Device Name Verista Imaging ISOCAM II Gamma Camera

Indications For Use:

Verista Imaging ISOCAM II Gamma Camera is intended to image the distribution of radionuclides in the body by means of photon radiation detector(s).

Prescription Use _X___ **OR** **Over-The Counter Use_____**
(Per 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081757